

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment of 03 April 2008 has been entered in full. Claims 1-10, 14, 15, 19-24, and 26 are canceled. Claims 11-13, 16-18, and 25 are under examination.

Withdrawn Objections And/Or Rejections

The objection to the specification for informalities as set forth at p.2 of the previous Office Action (mailed 03 October 2007) is *withdrawn* in view of the amendments correcting the informalities (received 03 April 2008).

The objection to claims 11, 12, and 25 for informalities as set forth at p.3 of the previous Office Action (mailed 03 October 2007) is *withdrawn* in view of the amendments correcting the informalities (received 03 April 2008).

The rejection of claims 16, 17, and 25 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 3-4 of the previous Office Action (mailed 03 October 2007) is *withdrawn* in view of the amended claims (received 03 April 2008).

The rejection of claims 11-13 and 25 under 35 U.S.C. § 101 as set forth at p.4 of the previous Office Action (mailed 03 October 2007) is *withdrawn* in view of the amended claims (received 03 April 2008).

The rejection of claims 11, 13, 16, and 25 under 35 U.S.C. § 102(e) as being anticipated by US 20030096288A1 (Wittamer et al.) as set forth at pp. 6-7 of the previous Office Action (mailed 03 October 2007) is *withdrawn* in view of the amended claims (received 03 April 2008).

The rejection of claims 11-13, 16-18, and 25 under 35 U.S.C. § 112, first paragraph, regarding scope of enablement as set forth at pp. 8-10 of the previous Office Action (mailed 03 October 2007) is *withdrawn* in view of the amended claims (received 03 April 2008).

The rejection of claims 11-13, 16-18, and 25 under 35 U.S.C. § 112, first paragraph, regarding inadequate written description as set forth at pp. 10-12 of the previous Office Action (mailed 03 October 2007) is *withdrawn* in view of the amended claims (received 03 April 2008).

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 12, 16, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9855508A2 (Sagami Chemical Research Center; published 10 December 1998). The basis of this rejection is set forth at pp. 5-6 of the previous Office Action (mailed 03 October 2007).

Applicant argues (p. 8, remarks of 03 April 2008) that the amino acid sequence disclosed in '508 does not anticipate the limitation of a COM polypeptide "consisting of" SEQ ID NO: 1. Applicant further argues that '508 does not disclose derivatives having

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SEQ ID NO: 1 and having at least 80% activity in the activity recited in the claims. This has been fully considered but is not found to be persuasive for the following reasons.

It is conceded that '508 does not teach a polypeptide consisting of the amino acid sequence in SEQ ID NO: 1.

However, the claims recite derivatives in the alternative which are disclosed in '508. Specifically, the derivative must have a core structure of SEQ ID NO: 1 and be no more than 150 amino acids in length. "Having" is interpreted as "comprising." Therefore, any protein comprising SEQ ID NO: 1 and being no more than 150 amino acids in length meets the structural limitations set forth in the claims. '508 teaches fragments of their full-length proteins lacking the N-terminal transmembrane domain at p. 7. SEQ ID NO: 17 of '508 comprises instant SEQ ID NO: 1 as follows:

| | |
|----------------------|--|
| instant SEQ ID NO: 1 | ELTEAQRRLQVALEEF |
| | |
| '508 SEQ ID NO: 17 | MRRLLIPLALWLGAVGVGVA ELTEAQRRLQVALEEF |
| instant SEQ ID NO: 1 | HKHPPVQWAFQETSVESAVDTFFPAGIFVRLEFKLQQ |
| | |
| '508 SEQ ID NO: 17 | HKHPPVQWAFQETSVESAVDTFFPAGIFVRLEFKLQQ |
| instant SEQ ID NO: 1 | TSCRKRDWKKPECKVRPNGRKRKCLACIKLGSEDKVL |
| | |
| '508 SEQ ID NO: 17 | TSCRKRDWKKPECKVRPNGRKRKCLACIKLGSEDKVL |
| instant SEQ ID NO: 1 | GRLVHCPIETQVLREAEHHQETQCLRVQRAGEDPHSF |
| | |
| '508 SEQ ID NO: 17 | GRLVHCPIETQVLREAEHHQETQCLRVQRAGEDPHSF |

| | |
|----------------------|-------------------------|
| instant SEQ ID NO: 1 | YFPGQF |
| | |
| '508 SEQ ID NO: 17 | YFPGQF AFSKALPRS |

From the alignment above, it is clear that SEQ ID NO: 17 in '508 "has" a core sequence of SEQ ID NO: 1. It also has an additional 20 amino acids at the N-terminus and an additional 9 amino acids at the C-terminus, for an overall length of 163 amino acids. The claims require a length of no more than 150 amino acids. At p. 7 of '508, it is stated that the proteins of the invention that are membrane proteins can be subjected to processing to leave a secreted form, and that these maturation proteins come within the scope of the invention. At pp. 54-55, '508 discloses that SEQ ID NO:17 has a transmembrane domain at the N-terminus, and refers to Figure 18 for a hydrophobicity/hydrophilicity plot, where it is clear that the N-terminal transmembrane domain is approximately 20 amino acids in length. Therefore, removal of this domain leaves a secreted peptide that meets the structural limitations of the claim, i.e., comprising SEQ ID NO: 1 and being no more than 150 amino acids in length. The claims require a functional limitation that the protein activates the GOR1-28 receptor of SEQ ID NO: 2 with an activity at least 80% of the native protein. It is reasonable to assume that the secreted form of SEQ ID NO; 17 of '508 n activity has this activity, since removal of a transmembrane domain would not remove any sequences that would interact with the receptor. Therefore, '508 teaches the derivatives recited in the claims.

Claim Objections

Claims 13, 17, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646